

**SYSTEM AND METHOD FOR SIMULATION AND MODELING OF  
BATCH PROCESS MANUFACTURING FACILITIES  
USING PROCESS TIME LINES**

***Abstract***

5           A system and method for the simulation and modeling of  
biopharmaceutical batch process manufacturing facilities using process time lines  
is described herein. The system employs a four-field delimited string code which  
specifies the unit identifier code and the iteration value for each of the three levels  
10           of scheduling cycle "Unit Operation Cycles," "Unit Operation Cluster Cycles,"  
and "Batch Cycles"-- of the biopharmaceutical drug production process being  
modeled. The method includes the step of selecting a sequence of unit operations  
wherein each of the sequence of unit operations has an identifier code. Next, a  
set of scheduling cycles is selected for each of the sequence of unit operations.  
15           A master table is then referenced, using the identifier code, to obtain operational  
parameters for each of the sequence of unit operations. A block flow diagram is  
then generated using the sequence of unit operations and the operational  
parameters. The method further includes generating a process time line using the  
operational parameters, the block flow diagram, and the set of scheduling cycles  
20           for each of the sequence of unit operations. The process time line--a time line for  
the beginning and ending times of each unit operation and its associated tasks for  
the entire biopharmaceutical drug production process--is used as a tool for batch  
processing and facility design.

#195108v1<SKGF\_DC1> -1606.0010003 - Continuation - AS FILED SPECIFICATI.wpd